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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,849	08/29/2001	Jeffrey A. Trogolo	281-37	5109

7590 04/06/2004

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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
	1615

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/940,849	TROGOLO ET AL.
	Examiner Carlos A. Azpuru	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 and 20-41 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>03052002</u> .	6) <input type="checkbox"/> Other: ____.

## **DETAILED ACTION**

Receipt is acknowledged of the information disclosure statement filed 12/26/2001 & 03/01/2002. A preliminary amendment and change of address letter were filed on 10/27/2003. An election also filed on 10/27/2003.

### ***Election/Restrictions***

Claims 10-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10272003.

### ***Claim Rejections - 35 USC § 112***

Claims 1-9, 20-41 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibiotic coating which is bilaminar, lubricious and hydrophilic, does not reasonably provide enablement for a unilaminar coating which is neither lubricious, nor hydrophilic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to claim the invention commensurate in scope with these claims. Applicant describes the essential elements of the invention at page 9, lines 5-6. These elements are essential to the practice of the invention but not included in the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5, 6, 8, 20-22, 24, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO00/30697 (WO'697)

WO'697 disclose an antibiotic substrate having a coating composition which is formed from a hydrophilic polymer which has antibiotic ceramic particles dispersed therein. These ceramic particles are preferably zeolite (see Abstract). Various articles used in the coating process are listed at page 7, lines 21-25, and include catheters. The WO'697 reference differs only in that polysaccharides are not expressly disclosed.

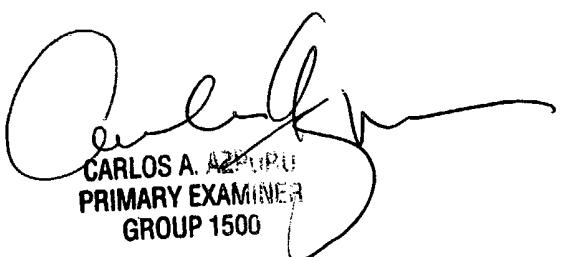
However, the general teaching of the use of a hydrophilic polymer in the coating process is found at page 4, lines 22-26. Those of ordinary skill would have known that any hydrophilic coating such as a polysaccharide, or particularly well known hydrophilic polysaccharides such as a hyaluronan could be used in the antibiotic coating as claimed with a reasonable expectation of similar antibiotic effects as taught by WO'697. The instant antibiotic coating comprising a polysaccharide and antibiotic ceramic dispersed therein would have been obvious given the disclosure of WO'697 which teaches the use of a hydrophilic polymer having antibiotic ceramics dispersed therein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0602. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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